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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,969	04/10/2006	Kwai Ming Cheung	010180.00047	1639

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EXAMINER	
CHU, YONG LIANG	
ART UNIT	PAPER NUMBER
1626	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/561,969	CHEUNG ET AL.	
	Examiner	Art Unit	
	YONG CHU	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/24/2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,8-23 and 25* is/are pending in the application.

4a) Of the above claim(s) *22 and 23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,8-21 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions on 11/24/2008 and 10/23/2008 have been entered. Upon entering the submission, claims 1, 8-23, and 25 are currently pending in the instant application. Claims 11-14, and 17-23 remain withdrawn as non-elected subject matter.

Response to RCE Submission

Claim rejection under 35 U.S.C.§112, 1st paragraph, written description

Applicants' amendment by cancelling the rejected subject matter has obviated the rejection.

Claim rejection under 35 U.S.C. §102(b)

Applicants' amendment has obviated the rejection.

Since all the rejections have been overcome, search and examination are expanded to the previously non-elected subject matter of all the product claims 1, 15-21, and 25. Method claims 22-23 remain withdrawn as non-elected subject matter. Therefore, claims 1, 15-21, and 25 are under examination on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 15-21, and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 1, 15-21, and 25 are rejected due to claiming a **"solvate"** and/or a **"hydrate"** of a compound of the Formula (IE) according to claim 1. The instant specification does not define "solvate" and "hydrate". According to Vippagunta et al., *Advanced Drug Delivery Reviews*, page 1, a **solvate** or a **hydrate** exist as crystalline forms. They are specific crystalline forms of a compound that can crystallize in different forms, and not all compounds can form crystalline. The specification does not reasonably provide enablement for forming crystalline of each of the compound list in the claims. Because of high level of unpredictability associated with crystalline of the compounds, a greater amount of evidentiary support is needed to fully satisfy the requirement of 35 U.S.C 112, first paragraph. It is noted that crystallization art is unpredictable, requiring each embodiment to be individually assessed for the possibility.

A disclosure should contain representative examples, which provide reasonable assurance to one skilled in the art that compounds fall within the scope of a claim will posses the crystalline form of the compound. To practice the claimed invention herein,

a person of skill in the art would have to engage in undue experimentation to test which compounds would form crystalline, with no assurance of success.

Claims 1, 15-21, and 25 are also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. According to Vippagunta et al., *Advanced Drug Delivery Reviews*, page 1, a "solvate" or a "hydrate" exists as crystalline forms with the specific orientation with the specific compound. However, such "solvate" is not described in the specification to reasonably convey one skilled in the art. There is even not a single working example on solvate disclosed in the specification in terms of a complex of variable stoichiometry formed by a solute or hydrate, and the crystal forms of the compounds according to claim 1.

Claims 1, 15-21, and 25 are rejected under 35 U.S.C. 112, first paragraph, because the specification although enabling for the compounds of formula (IE) for HSP90 inhibitory activity does not reasonably provide enablement for use all the numerous number of the claimed compounds in claim 1 **as a human or veterinary medicine**. The specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use these claims.

As stated in MPEP 2164.01(a), "there are many factors to be considered when determing whether there is sufficient evidence to support a determination that a

disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue".

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

The Nature of the Invention

The nature of the invention in Claims 1, 15-21, and 25 are a compound of the Formula (I) according to claim 1 for use as a human or veterinary medicine.

The Breadth of the Claims

The breadth of the claims encompasses compounds or composition of formula (IE) according to claim 1 for use as a medicine. The applicable rule for interpreting the claims is that "each claim must be separately analyzed and give its broadest reasonable interpretation in light of and consistent with the written description." See MPEP 2163(II)(I), citing In re Morris, 127 F.3d 1048, 1053-1054; 44USPQ2d 1023, 1027 (Fed. Cir. 1997).

The State of the Prior Art

The state of the prior art does not support Applicant's claim for the use of the compound as a medicine. The instantly claimed compounds are small molecular

compounds, and are intend to be used for treating various diseases according to the instant specification. According to Wikepedia, **medicine**, also referred to as medication, is usually a **drug** or any other substance used to treat disease or to relieve pain, anxiety, cancer, or any form of perceived discomfort. In the United States, a small molecular medicine, especially used for treating diseases such as cancer is regulated by FDA. To be marketed as medicine, a chemical compound or a composition has to go through phase I-III of clinical trial under the FDA guidelines for safety and efficacy evaluations.

The Level of Skill in the Art

The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention for use as a medicine is required to be individually assessed and approval by FDA.

The predictability or lack thereof in the art

Because of high level of unpredictability associated with approved composition to administering to human, a greater amount of evidentiary support is needed to fully satisfy the requirement of 35 U.S.C 112, first paragraph. It is noted that pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427 F.2d 833, 166USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statue. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

The Amount of Direction or Guidance Present

The specification does not provide the direction for the claimed compound for use as medicine for administering to human for various diseases.

The Presence or Absence of Working Examples

A disclosure should contain representative examples, which provide reasonable assurance to one skilled in the art that compounds fall within the scope of a claim will posses the alleged activity. See In re Riat et al. (CCPA 1964) 327 F2d 685, 140USPQ 471; In re Barr et al. (CCPA 1971) 444 F 2d 349, 151 USPQ 724. The instant specification has demonstrated that some of the compounds have some HSP90 inhibitory activity at pages 24-25 of the specification. But the specification does not show that all the compounds are safe and affect enough to be used as a medicine.

Therefore, in view of the Wands factors and In re Fisher (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test which compound would be used as a medicine. Applicant may overcome this rejection by **deleting the intend to use** term "as a human or veterinary medicine" in claim 1 or pointing out where in the specification support for the in tend to use can be found.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

regards as the invention. Specifically, the definition of R_2 is "a non aromatic carbocyclic or heterocyclic ring". However, it is not clear R_2 is defined as "a non-aromatic carbocyclic or a non-heterocyclic ring" or "a non-aromatic carbocyclic or a heterocyclic ring". A heterocyclic ring includes heteroaryl and non-heteroaryl. The Examiner interprets the term as the latter one.

Claims 15-16 recite the limitation "R_2 is phenyl" in claim 1. There is insufficient antecedent basis for this limitation in the claim, because R_2 is a non aromatic carbocyclic ring, which can not be phenyl.

Conclusion

No claims are allowed.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Chu whose telephone number is 571-272-5759. The examiner can normally be reached between 7:00 am - 3:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Status Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Yong Chu/
Patent Examiner
Art Unit 1626